REMARKS

Applicants respectfully request reconsideration of the application in view of the foregoing amendments and the following remarks.

Claim Status

Claims 1, 6, 9, 13 and 24 are amended. Support for these amendments is found throughout the application as filed, including paragraph [0026] for the amendment to claim 1, and paragraph [0046] for the amendment to claim 13. Thus, no new matter is added. These amendments are made without prejudice or disclaimer and Applicants reserve the right to pursue any non-elected subject matter in one or more continuing applications with the same priority rights as the instant application.

Applicants respectfully request entry of these amendments after final because they place the claims in condition for allowance, or at the very least in better condition for appeal. Moreover, they are not believed to require an additional search. For example, the recitations added to claim 1 are related to the embodiments recited in claim 4.

Upon entry of the amendments, claims 1-9, 11-22 and 24-27 will remain pending in the application, and it is these claims that are presented for reconsideration.

Rejections under 35 U.S.C. § 112, second paragraph

Although page 2 of the Office Action states that claims 6, 7, 9, 13, 22, and 24 are rejected under § 112, second paragraph, a telephone call to the Examiner confirmed that claims 6, 7 and 22 are no longer subject to a § 112 rejection.

Claims 9, 13 and 24 were rejected for alleged indefiniteness with respect to the recitation of derivatives. While Applicants disagree with these rejections for the reasons set forth in their previous response, Applicants have amended these claims to cancel the recitation of derivatives. Accordingly, these rejections are moot.

Claim 13 was rejected for alleged indefiniteness with respect to the recitation of "a component of an essential oil." While Applicants disagree with these rejections for the

reasons set forth in their previous response, Applicants have amended this claim to cancel the language at issue. Accordingly, this rejection is moot.

Rejections under 35 U.S.C. § 103

A. Rejection over Ohno & Geyer

Claims 1-9, 11-19 and 24-27 were rejected under 35 U.S.C. § 103 (a) as allegedly obvious in view of Ohno and Geyer. Office Action, pages 3-5 and 9-10. Applicants respectfully traverse this rejection in as much as it may be applied to the instant claims.

Instant claim 1 (from which the other rejected claims depend) recites an immediate-release pharmaceutical or nutraceutical micronized powder for mucosal delivery of at least one active agent, having a particle size of at most 100 μm and comprising (a) at least one active substance; (b) at least one wetting agent; (c) at least one diluent; and (d) an antistatic agent comprising from 0.01 % to 10% by weight of the total weight of the composition, wherein the powder has a dissolution kinetic of less than 30 seconds in an aqueous medium at pH 5 to 9, and, upon mucosal administration, releases the active substance(s) at the mucosal site. The combination of Ohno and Geyer does not teach or suggest such a powder.

Ohno is cited for teaching solid pharmaceutical compositions for buccal dissolution. The composition comprises an active agent, erythritol, crystalline cellulose, and a disintegrant. As recognized at page 4 of the Office Action, Ohno does not teach or suggest a micronized powder having a particle size of at most 100 μm, as recited in the instant claims, but instead relies on the combination of erythritol, crystalline cellulose, and disintegrant to provide fast-dissolving properties. *See, e.g.*, Ohno page 2, lines 39-42. While the Office Action cites Geyer for teaching particles within the range of 10-150 μm, the combination of Ohno and Geyer would not have led the skilled artisan to the present invention.

At the outset, Applicants emphasize that the skilled artisan would have no reason to combine the teachings of Ohno with those of Geyer, or to modify the teachings of Ohno based on Geyer, because the references are directed to different types of pharmaceutical

compositions. Ohno is directed to solid pharmaceutical compositions for buccal dissolution, while Geyer is directed to a chewable composition for oral delivery of unpalatable drugs. Ohno's compositions are designed such that after they are "orally administered, [they] intrabucally dissolve or disintegrate without being swallowed." Ohno, page 5. In contrast, Geyer teaches that its composition facilitates the process of chewing "before swallowing," and the active agent is to be absorbed through the digestive tract, after the composition is swallowed. *See,* Geyer, col. 2, lines 5-11. Indeed, Example 9 of Geyer is said to demonstrate that the active agent "is still available for absorption in the gut," further underscoring the differences between its compositions and those of Geyer.

Even if someone skilled in the art did look to Geyer to modify Ohno, the present invention would not be suggested. The Examiner cites column 4 of Geyer for teaching particles within the range of 10-150 μm, but this portion of Geyer is describing a spray congealing process for making the lipid/drug component of Geyer's composition, and does not discuss the particle size of Geyer's final composition. This process is illustrated in Example 10, which reports that a lipid/drug component with a median particle size of 118 μm was obtained and then combined with other components that were prepared by grinding and blending. Thus, there is no teaching or suggestion in Geyer of a final composition which has a particle size in the range of 100 μm, *e.g.*, there is no teaching or suggestion in Geyer of a micronized powder comprising at least one active substance, at least one wetting agent, at least one diluent and an antistatic agent, and having a particle size of at most 100 μm, as recited in the instant claims.

Because those skilled in the art would not have combined the cited references in the manner asserted in the Office Action, and because the cited combination fails to make out a prima facie case of obviousness, the §103 rejection based on Ohno and Geyer is improper and should be withdrawn.

B. Rejection over McCarty & Geyer

Claims 1-9, 12-19, and 24-27 were rejected under 35 U.S.C. § 103 (a) as allegedly obvious in view of Geyer and McCarty. Office Action, pages 5-7 and 10. Applicants respectfully traverse this rejection in as much as it may be applied to the instant claims.

Although the Office Action appears to rely on Geyer as the primary reference, this is improper because Geyer is directed to a different type of composition (oral) than that recited in the instant claims (mucosal). Those skilled in the art looking to make an immediate-release pharmaceutical or nutraceutical micronized powder for mucosal delivery of at least one active agent would have no reason to turn to Geyer, because its compositions are designed to facilitate oral administration of the active agent. Indeed, Geyer's composition achieves absorption of the active agent in the gut, whereas the instant claims recite a powder that, upon mucosal administration, releases the active substance(s) at the mucosal site.

McCarty is cited for teaching a fast dissolving buccal tablet. As taught at columns 1-2, McCarty relies on a lubricant and soluble excipient to achieve rapid buccal delivery. Like Ohno, McCarty does not teach or suggest the use of micronized particles, let alone a micronized powder having a particle size of at most 100 μm, as recited in the instant claims.

While the Office Action again relies on Geyer for such teachings, the combination of McCarty and Geyer does not teach or suggest the present invention, for at least the same reasons that the combination of Ohno and Geyer fails to do so.

First, the skilled artisan would have no reason to combine the teachings of McCarty with those of Geyer, or to modify the teachings of McCarty based on Geyer, because the references are directed to different types of pharmaceutical compositions. McCarty (like Ohno) is directed to tablets for buccal administration, while Geyer is directed to a chewable composition for oral delivery. As taught at column 1, McCarty's tablets are designed to "rapidly deliver[] the active ingredient through the buccal route," and are useful for delivery of drugs that are not suitable for oral administration, such as estradiol. In contrast, as

explained above, Geyer's compositions are designed for oral administration and absorption of the active ingredient in the gut.

Second, even if someone skilled in the art did look to Geyer to modify McCarty, the present invention would not be suggested. As discussed above, while Geyer teaches that the lipid/drug component of its composition may be micronized, Geyer does not teach or suggest that its final composition is micronized. Thus, there is no teaching or suggestion in Geyer of a micronized powder comprising at least one active substance, at least one wetting agent, at least one diluent and an antistatic agent, and having a particle size of at most 100 μm, as recited in the instant claims.

Because those skilled in the art would not have combined the cited references in the manner asserted in the Office Action, and because the cited combination fails to make out a prima facie case of obviousness, the §103 rejection based on McCarty and Geyer is improper and should be withdrawn.

C. Rejection over McCarty, Geyer & Stamm

Claim 11 was rejected under 35 U.S.C. § 103 (a) as allegedly obvious in view of McCarty, Geyer and Stamm. Office Action, pages 7-8. Applicants respectfully traverse this rejection in as much as it may be applied to the instant claims.

This rejection relies on McCarty and Geyer as the primary references, and cites Stamm for teaching an antistatic agent recited in claim 11, *e.g.*, colloidal silica. As shown above, however, the combination of McCarty and Geyer does not teach or suggest the present invention, i.*e.*, does not teach or suggest an immediate-release pharmaceutical or nutraceutical micronized powder for mucosal delivery of at least one active agent, having a particle size of at most 100 μm and comprising (a) at least one active substance; (b) at least one wetting agent; (c) at least one diluent; and (d) an antistatic agent comprising from 0.01 % to 10% by weight of the total weight of the composition, wherein the powder has a dissolution kinetic of less than 30 seconds in an aqueous medium at pH 5 to 9, and upon mucosal administration,

releases the active substance(s) at the mucosal site. Combining these references with Stamm does not teach or suggest the present invention, let alone the embodiments recited in claim 11.

As noted at page 7 of the Office Action, Stamm teaches a composition comprising micronized fenofibrate. Like Geyer, however, Stamm does not teach or suggest that its final composition is a micronized powder having a particle size of at most 100 μm. For example, while Stamm uses micronized fenofibrate, there is no teaching or suggestion in Stamm that its colloidal silica is micronized. To the contrary, Stamm teaches that the colloidal silica is used in an "outer phase" that is coated on the active ingredient core. *See, e.g.*, Stamm, col. 4, lines 52-59, and Example 1. Even the core of Stamm's product comprises particles sizes greater than the 100 μm recited in the instant claims. For example, as shown in Example 1, micronized fenofribrate (5 μm) is combined with coarse crystal lactose monohydrate (100 - 400 μm), PVP and sodium lauryl sulfate, and the resulting mixture is passed through a 350 μm sieve before being sprayed onto lactose, and then coated with the outer phase comprising colloidal silica. Thus, Stamm does not teach or suggest a micronized powder comprising (a) at least one active substance; (b) at least one wetting agent; (c) at least one diluent; and (d) an antistatic agent comprising from 0.01 % to 10% by weight of the total weight of the composition, and having a particle size of at most 100 μm, as recited in the instant claims. Moreover, Stamm's composition, like Geyer's, is designed for oral administration, *see,e.g.,* Stamm, col. 5, lines 29-30, and there is no teaching or suggestion in Stamm of a micronized powder for mucosal delivery of at least one active agent, that upon mucosal administration, releases the active substance(s) at the mucosal site.

Moreover, even if one looked to Stamm just for its teaching of colloidal silica, one would not find a reason to provide the colloidal silica as a component of a micronized powder having a particle size of at most 100 μm, but would understand that the colloidal silica should be provided separately from the micronized active agent, as part of a coating.

Because the combination of McCarty, Geyer and Stamm would not lead the skilled artisan to the present invention, this §103 rejection is improper and should be withdrawn.

C. Rejection over Ohno, Geyer & Mundt

Claims 20-22 were rejected under 35 U.S.C. § 103 (a) as allegedly obvious in view of Ohno, Geyer and Mundt. Office Action, pages 8-9. Applicants respectfully traverse this rejection in as much as it may be applied to the instant claims.

This rejection relies on Ohno and Geyer as the primary references, and cites Mundt for teaching packaging configurations as recited in claims 20-22. As shown above, the combination of Ohno and Geyer does not teach or suggest the micronized powder of the present invention, and combining Mundt with these references does not remedy their deficiencies.

Because those skilled in the art would not have combined Ohno and Geyer in the manner asserted in the Office Action, and because the combination of Ohno, Geyer and Mundt fails to make out a prima facie case of obviousness, this §103 rejection is improper and should be withdrawn.

CONCLUSION

Applicants believe that the application is in condition for allowance, and an early notice to that effect is earnestly solicited.

Should there be any questions concerning this application, or should any issues remain, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,

Date November 17, 2004

By _____

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